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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/651,852	08/29/2003	Richard G. Cartledge	52817/291339	8128
23370	7590	02/17/2006	EXAMINER	
JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET ATLANTA, GA 30309			POUS, NATALIE R	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

E

Office Action Summary

Application No.

10/651,852

Applicant(s)

CARTLEDGE ET AL.

Examiner

Natalie Pous

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 22 is poorly worded, making it difficult to understand the scope of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 20, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (US 6168616).

Regarding Claim 1, Brown teaches an apparatus for positioning an annular implant (50) about the perimeter of an anatomic orifice, comprising: a first shaft (90) having proximal and distal ends; a second shaft (20) having proximal and distal ends and being slidably received within said first shaft (Column 2, proximate lines 61-67), a plurality of arms (120), each of said arms having a distal end deflectably mounted to said distal end (10) of said second shaft; at least one deflection device (170) configured to deflect a proximal end of each of said plurality of arms away from said second shaft when relative movement between said first and second shaft is effected (fig. 4); a device to do at least one of, holding an annular implant (50) to said proximal ends of said arm; or adjust an annular implant for adjusting the circumference of said annular implant.

Regarding Claims 20 and 21, Brown teaches the apparatus of claim 1, wherein second shaft (20) comprises a central lumen (it is noted that second shaft 20 is defined as a tube, which inherently has a central lumen), extending from a location distal to said distal end of said first shaft (fig. 1) to a location proximal to said proximal end of said first shaft (Column 1, proximal lines 30-40)

Regarding Claim 22, Brown teaches the apparatus of claim 1, wherein the device to do at least one of holding an annular implant (50) to said proximal ends of said arms (120) or adjust an annular implant for adjusting a circumference of said annular implant (Column 2, proximate lines 61-67), includes a separate holding (40) device and a separate adjustment device (90).

Claims 1, 15, 16 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Marin et al. (US 5443477).

Regarding Claim 1, Marin teaches an apparatus for positioning an annular implant (48) about the perimeter of an anatomic orifice, comprising: a first shaft (62) having proximal and distal ends; a second shaft (80) having proximal and distal ends and being slidably received within said first shaft (Column 5, proximate lines 47-65), a plurality of arms (82), each of said arms having a distal end deflectably mounted to said distal end of said second shaft (80) see fig. 5; at least one deflection device (84) configured to deflect a proximal end of each of said plurality of arms away from said second shaft when relative movement between said first and second shaft is effected (fig. 4); a device to do at least one of, holding an annular implant (48) to said proximal ends of said arm; or adjust an annular implant for adjusting the circumference of said annular implant.

Regarding Claim 15, Marin teaches the apparatus of claim 1, wherein at least one deflection device includes a plurality of struts (84), each of said struts having a proximal end (120) deflectably mounted to said distal end of said first shaft (62) and having a distal end deflectably mounted (118) to a corresponding one of said plurality of arms (82).

Regarding Claim 16, Marin teaches the apparatus of claim 15, wherein said distal end (96) of each of said plurality of arms (82) is pivotably mounted to said distal end of said second shaft (80), wherein said proximal end (120) of each of said plurality of struts (84) is pivotably mounted to said first shaft (62); and wherein said distal end (118) of

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said plurality of struts (84) is pivotably mounted to a corresponding one of said plurality of arms (fig. 4).

Regarding Claim 22, Marin teaches the apparatus of claim 1, wherein the device to do at least one of holding an annular implant (48) to said proximal ends of said arms (82) or adjust an annular implant for adjusting a circumference of said annular implant includes a separate holding device and a separate adjustment device.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown in view of Glukhovsky et al. (US 6986738).

Brown teaches all aspects of preceding dependent claim 1, but fails to disclose wherein at least one sensor extending distally to said annular implant when an annular implant is mounted to said distal ends of said arms. Glukhovsky teaches a system for

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maneuvering a device in vivo wherein a sensor (14) is located on the distal end of a device (12) inserted into the vasculature in order to enhance a practitioner's ability to safely and easily detect internal body features and occurrences with minimal intrusion (column 1, proximate lines 15-20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the distal end of Brown with a sensor as taught by Glukhovsky in order to enhance a practitioner's ability to safely and easily detect internal body features and occurrences with minimal intrusion.

Claims 3-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Brown and Glukhovsky as applied to claims 1 and 2 above, and further as a matter of obvious design choice. Glukhovsky discloses wherein sensor (14) may detect in vivo conditions in body lumens, such as, temperature, pH or pressure, and transmit a signal using radio or wire connection (Column 4, proximate lines 7-20). Also, image sensors are used for the visual inspection of body lumens or cavities (column 1, proximate lines 23-30), and further, the sensing device may be any suitable sensing device known in the art to perform these functions. Further it is well known in the art to add a radiopaque material to an intravascular device in order to use imaging techniques to view the device. It would therefore be obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Brown and Glukhovsky by employing the touchdown sensor of claims 3-10, the microswitch of claim 11, the fiberoptic sensor of claim 12 or the electronic sensor of claims 13 and 14 in the position of sensor (14) as disclosed by Glukhovsky in order to measure different characteristics of the vessel wall and lumen.

Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown in view of Mikus et al. (US 20020151967).

Regarding the limitation of an outer third shaft, Brown teaches all limitations of claim 1 as previously described, but fails to disclose a third shaft having proximal and distal ends said first and second shafts being slidably received within said third shaft such that said plurality of arms and said means for deflecting said plurality of arms are enclosed within said distal end of said third shaft. It is well known in the art to provide a stent deployment system with an outer protective sheath in order to prevent abrasion between the stent and body wall as the device is directed through torturous body pathways. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Brown with an outer protective sheath or catheter in order to prevent abrasion between the stent and body wall as the device is directed through torturous body pathways.

Regarding the limitation wherein a radially extending key and corresponding channel is present in the shafts, Brown teaches all aspects of claim 1, but fails to disclose wherein one of the first and second shafts has a radially extending key and the other of said first and second shafts has a corresponding recess for receiving said key. Mikus teaches a stent delivery system wherein the sheath may be rotationally fixed relative to either the inner catheter or outer catheter tube, with, for example, a longitudinally oriented tongue and groove structure or spline and keyway structure mating the sheath to the outer catheter tube. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Brown

with a longitudinally oriented tongue and groove structure or spline and keyway structure mating the sheath to any of the shafts as taught by Mikus in order to inhibit rotational movement with respect to the shafts.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRP
2/8/06



(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER

2/15/06